# AORN Position Statement on the Role of the Health Care Industry Representative in Perioperative Settings

## POSITION STATEMENT

AORN acknowledges and values the role of the health care industry representative in perioperative settings. AORN believes:

- A health care industry representative may be present during an operative or other invasive procedure under conditions prescribed by the health care organization and in compliance with accreditation requirements and local, state, and federal regulations.

- Perioperative registered nurses (RNs), perioperative administrators, and health care industry representatives are accountable to advocate for patient safety; workplace safety; and the patient's right to information, privacy, and confidentiality when a health care industry representative is present during an operative or other invasive procedure.

- Health care facilities should educate physicians regarding the credentialing requirements for health care industry representatives.[1]

- Health care facilities and industry partners should be transparent and avoid conflicts of interest. If a conflict of interest exists, then the facility and industry partner should manage the conflict appropriately and with full disclosure as needed.[2]

- The following precepts should be used to guide an interdisciplinary team in developing and periodically reviewing policies and procedures related to health care industry representatives in operating or invasive procedure settings.

## ROLE OF THE PERIOPERATIVE NURSE

Perioperative nursing practice is an art and a science that includes scientific principles, best practices, and patient advocacy. The perioperative RN is accountable for the patient's outcome as a result of the nursing care delivered during the operative or other invasive procedure. Core nursing activities (eg, assessment, diagnosis, outcome identification, planning, evaluation), as indicated by licensure, may not be performed by anyone who is not a nurse employed by the health care organization. When a health care industry representative is present during an operative or other invasive procedure, perioperative RNs should

- advocate for the patient's safety, privacy, dignity, and confidentiality in all phases of perioperative care[3,4];
- verify that all members of the perioperative team have received education and completed competency verification on new procedures, techniques, technology, and equipment before their use in an operative or other invasive procedure;

- verify that new or loaned equipment has been approved by the health care organization's service provider[5];
- verify that loaned instruments have been through the health care organization's terminal sterilization process before use[5];
- follow facility policy and federal, state, and local regulations regarding obtaining informed consent, including whether the patient must give consent for the health care industry representative to be present during the operative or other invasive procedure;
- verify that the health care industry representative has been credentialed according to the health care organization's policy[6];
- verify that the health care industry representative is wearing identification, preferably a photo identification badge; surgical attire; and personal protective equipment as described in AORN guidelines and the health care organization's policies[7,8];
- monitor the health care industry representative's activities and facilitate the representative's service to the perioperative team during the operative or other invasive procedure[9,10];
- monitor infection prevention practices and limit the movement and number of people in the operating or invasive procedure room during the procedure to prevent increased airborne contamination[9]; and
- document the health care industry representative's presence, including the representative's name, company, and time in the room, in the intraoperative nursing record according to the health care organization's policy.

**ROLE OF THE PERIOPERATIVE ADMINISTRATOR**

Perioperative administrators in all settings (eg, acute care hospitals, ambulatory surgery centers, office-based surgery centers) are accountable for ensuring that a structured process exists to provide education on procedures, techniques, technology, and equipment to health care professionals practicing within the operative or other invasive procedure setting.[3] Administrators should collaborate with the organization's risk manager or legal counsel to develop policies and procedures that are specific to the health care industry representative's role in the operating or invasive procedure room; advocate for patient safety and workplace safety; and ensure compliance with applicable federal, state, and local laws.[11-15] Policies and procedures should include

- the informed consent process (eg, every patient should be informed about the presence of a health care industry representative in the operating or invasive procedure room) according to federal, state, and local regulations[10,11,16,17];
- the specific conditions under which the health care industry representative may be present during an operative or other invasive procedure[6,10];
- a policy statement that all representatives will follow the same guidelines and restrictions whether or not the health care industry representative has previous perioperative experience (eg, RN, surgical technologist);
- restrictions specifying that health care industry representatives do not provide direct patient care and are not allowed to participate in sterile field activities including opening of sterile supplies;
- processes for credentialing health care industry representatives who have specialized education to perform calibration or synchronization to adjust or program devices (eg, implanted electronic devices, radio-frequency devices, lasers) under the direction of the physician;
- processes for informing the perioperative team that a health care industry representative will be present during a specific procedure;
- processes for inspecting loaned equipment and sterilizing loaned instruments before the invasive procedure[10];

- requirements for and documentation of tuberculosis (TB) testing and vaccinations as recommended by AORN and the health care organization's infection prevention personnel[6,8,18];
- orientation requirements, including
  - completion of a perioperative orientation class (eg, the AORN OR Protocol®)[19];
  - facility policies and procedures related to attire,[7] traffic patterns,[9] and ordering and delivery of supplies and equipment;
  - the Health Insurance Portability and Accountability Act (HIPAA)[16] and all matters relating to patient rights and confidentiality[3];
  - hand hygiene practices[20];
  - expected conduct related to aseptic principles and sterile technique[9];
  - Occupational Safety and Health Administration (OSHA) requirements for prevention of infectious disease transmission and exposure to bloodborne pathogens[8,21];
  - occupational safety information (eg, biohazardous waste, electrical hazards, radiation) and other safety protocols[6,22,23];
  - fire safety and evacuation routes[23]; and
- requirements related to the AdvaMed Code of Ethics on Interactions with Health Care Professionals[6,24];
- a list of individuals (eg, supply chain management personnel) responsible for authorizing the health care industry representative's presence; and
- the time frame during which the health care industry representative will be allowed in the perioperative suite (eg, the time frame may be at the discretion of the RN circulator based on the education and patient care needs, the representative may be in the procedure room only during set times)[10];
- processes for
  - vendor sign-in/check in;
  - making the appointment;
  - introduction of new products or devices including trials;
  - managing consigned goods[24];
  - obtaining permission from the surgeon;
  - obtaining authorization in advance from the health care organization–designated authority when an experienced health care representative will be accompanied by another representative for the purpose of orientation; and
  - bringing equipment and instruments for inspection or sterilization before use, to include adhering to the required time frame necessary to meet sterilization and biological monitoring parameters; and
- requirements that the health care industry representative must meet before being admitted into the procedure room, including
  - appropriate identification (eg, a photo identification badge)[7,10];
  - completion of orientation requirements as designated in the health care organization's policies and procedures[6,10]; and
  - attestation from the health care industry representative's company that background verification at local, state, and federal levels was performed upon hire, including a search of the national sex offender registry, the Office of the Inspector General sanctions list, the US General Services Administration excluded parties list, the US Food and Drug Administration disbarment list, and the global sanction and watch list; employment verification; and a drug screen.[6]

**ROLE OF THE HEALTH CARE INDUSTRY REPRESENTATIVE**

By virtue of their education, knowledge, and expertise, health care industry representatives have a valid, but restricted, role in the operative or other invasive procedure setting. Health care industry representatives hold a variety of positions (eg, clinical consultants, sales representatives, technicians, repair/maintenance personnel) in their own organizations. When in the operating or invasive procedure room, a representative should

- advocate for patient safety, workplace safety, and patient privacy;
- provide technical support in accordance with the health care organization's policies and procedures, and federal, state, and local regulations[6];
- conduct formal inservice programs or one-on-one instruction for the perioperative team to provide essential education, technical training, and assistance related to the device or product to be used from the representative's organization;
- provide education for perioperative team members about new procedures, techniques, technology, and equipment before it is used in an operative or other invasive procedure;
- provide education to sterile processing technicians regarding processing the equipment (eg, cleaning, disassembly, re-assembly, inspection, preparation, sterilization);
- comply with a defined, restricted role that does not include performing actions as a part of the clinical team, participating in sterile field activities, or accepting requests to perform tasks outside of his or her approved role as outlined in the health care organization's policies and procedures[10];
- present documentation to verify specialized education and the health care organization's approval if he or she will be performing calibration or synchronization to adjust or program devices (eg, implanted electronic devices, radio-frequency devices, lasers) under the supervision of the physician[6,10];
- comply with the health care organization's policies and procedures, related to
  - vendor sign-in/check in;
  - appointment requirements;
  - introduction and trials of new products/devices;
  - managing consigned goods[24];
  - obtaining permission from the surgeon;
  - obtaining authorization from the designated authority;
  - obtaining authorization in advance from the health care organization–designated authority when an experienced health care representative will be accompanied by another representative for the purpose of orientation;
  - the time frame for delivery of equipment, instruments, and instructions for use before procedure scheduled start time; and
  - wearing proper identification, preferably a photo identification badge[6,7,10];
- provide documentation of a TB test and vaccinations as required by the health care organization's policies and procedures and infection prevention personnel[6,8,18];
- comply with the AdvaMed Code of Ethics on Interactions with Health Care Professionals[6,243]; and
- comply with the health care organization's policies and procedures for orientation and requirements for ongoing education on
  - the devices, equipment, or supplies specific to the procedure in which he or she will be involved[6];
  - patient rights and confidentiality requirements included in HIPAA[16] and all matters relating to patient rights and confidentiality[3];
  - expected attire in the perioperative or invasive procedure area[7];
  - traffic patterns in the perioperative suite[6,9];
  - hand hygiene practices[20];
  - expected conduct related to aseptic principles and sterile technique[9];
  - OSHA requirements for prevention of infectious disease transmission and exposure to bloodborne pathogens[8,21];

- occupational safety information (eg, biohazardous waste, electrical hazards, radiation) and other safety protocols[6,22,23]; and
- fire safety, disaster management, and evacuation routes.[23]

**RATIONALE**

Operating and invasive procedure rooms are among the most potentially hazardous of all clinical environments and are subject to strict regulations, clinical practice guidelines, and standards of care to preserve patient and personnel safety. Clinicians using equipment with which they are unfamiliar or that they have not received education to use may create hazards for both patients and perioperative team members. Misuse of complex technology can cause injury or even death. Facilities have been cited and fined for not following state and federal regulations.[12,14,25]

Using a systematic method to provide perioperative team members with education, training, and instruction related to new technology, equipment, techniques, and procedures is essential for safe patient care. The value the health care industry representative brings to the perioperative team is education and on-site expertise to help them make critical, real-time choices. Health care industry representatives and health care professionals mutually benefit when an educated sales representative is present in the operating room when equipment or an implant from the manufacturer he or she represents is being used. Technical support and instruction provided by health care industry representatives can potentially decrease the time of the operative or other invasive procedure and facilitate the attainment of optimal patient outcomes.

When policies and procedures that address the role of the health care industry representative in the operating or invasive procedure room are implemented, RNs, administrators, and health care industry representatives can be consistent in advocating for patient safety and workplace safety; helping to prevent health care–associated infections; and maintaining patients' rights to information, privacy, and confidentiality when health care industry representatives are present during operative or other invasive procedures. Health care organizations should be aware of the potential influence of industry representatives on physicians' product use and selection practices to prevent products being brought into the facility that are not compliant with existing contracts and potential conflict of interest issues that may arise.[2,26-28]

National organizations recommend that equipment be inspected and approved by the health care organization's service provider before use[29] and that loaned instruments be sterilized by the receiving organization before use.[5,30] AORN recommends that members of the perioperative team use equipment and supplies according to the manufacturer's instructions for use.[23,31-34] Health care industry representatives play a key role in educating perioperative team members in the use of new and existing technologies, equipment, and supplies based on the manufacturer's instructions for use. Notifying perioperative leaders in advance and having the equipment or instruments inspected and processed before the time of education, demonstration, and use reduces the risk for delays and facilitates productivity.

**Glossary**

*Health care industry representatives:* Employees of health care product companies (eg, clinical consultants, sales representatives, technicians, repair/maintenance personnel).

*Service provider:* An entity with the responsibility to provide inspection or other maintenance services for a specific piece of equipment. A service provider may be a department within the health care organization or a contracted provider.

*Informed consent*: "Agreement or permission accompanied by full notice about the care, treatment or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents to or refuses such a procedure or treatment."[35]

*Conflict of interest:* Exists when a health care professional "with responsibility to others is influenced, consciously or unconsciously, by financial, personal, or other factors which involve self-interest."[36]

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